

Application No.10/765,269
Supplemental Response to Office Action dated March 1, 2007
Paper dated August 1, 2007
Attorney Docket No. 0470-040032

REMARKS

Claims 17 through 36 are pending in this application. Claims 17 through 32 have been withdrawn as non-elected subject matter. Claim 33 has been amended, and claims 34 through 36, which depend on claim 33, are amended vis-à-vis the amendment to claim 33. Specifically, claim 33 has been amended to recite that the claimed peptide preparation contains less than 200 gliadin parts per million.

Rejection under 35 U.S.C. § 112

Claims 33 through 36 stand rejected under 35 U.S.C. § 112, first paragraph as purportedly failing to enable one skilled in the art to practice the claimed invention. The enablement requirement refers to the requirement “that the *specification* must describe how to make and how to use the invention,” not that the claims by themselves enable one skilled in the art to make and use the claimed invention (MPEP § 2164 *et seq.*, emphasis added). In this case, the Specification describes how to make the claimed peptide preparation because the Specification identifies the steps of making the claimed peptide preparation. (For example, see Specification at page 6, line 28 through page 8, line 14). Therefore, the Specification enables one skilled in the art to make and use the claimed invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 33 through 36 stand rejected under 35 U.S.C. § 102 as purportedly anticipated by Auriol et al. (WIPO, PCT, International Publication Number WO93/18180) (“Auriol”). The claimed invention, as amended, is novel over Auriol because Auriol does not teach a gluten-free product, particularly a product that contains less than 200 gliadin part per million, nor does it teach hydrolyzing a gliadin component of gluten wheat protein.

To further support this, Applicants submit herewith a Declaration by Edward Allen Hunter, one of the inventors named in this Application. The Declaration evidences that Auriol Example 2 is analogous to Experiment 5 in the Specification, and that Auriol Example 2

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produces a product that is not gluten-free because the product has more than 200 gliadin parts per million.

Auriol Example 2 teaches a product that contains more than 300 gliadin parts per million. The product taught by Auriol Example 2 is made by first hydrolyzing wheat gluten with Alcase at a pH of 8. The hydrolysate is then re-suspended in 70% n-propanol, and more Alcase is added. The pH is then adjusted to 5.1, and the mixture is incubated for 20 hours at 25°C. The n-propanol is removed, and the remaining aqueous suspension is adjusted to a pH of 6.0 before being filtered (see Declaration at ¶ 4).

In sum, Auriol Example 2 teaches alcoholysis of wheat gluten at a pH of 8.0 and 5.1, adjusting the pH of the solution to 6.0, and filtering the solution. This is similar to Experiment 5 in the instant Specification, which describes an experiment where the pH of the solution was adjusted to 6.5 just before filtration and the resulting product contained more than 300 gliadin parts per million (Specification at page 6, lines 20-26). Therefore, although Auriol does not specifically state the concentration of gliadin in the final product, it is anticipated that Auriol Example 2, which is analogous to Experiment 5 in this Application, would also produce a product having more than 300 gliadin parts per million (see Declaration at ¶ 5). Since Auriol Example 2 teaches a product having more than 300 gliadin parts per million, it does not teach a product having less than 200 gliadin parts per million. Accordingly, Auriol does not teach the invention as recited in claims 33-36. For this reason, Applicants respectfully request that the rejection based on Auriol be reconsidered and withdrawn.

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CONCLUSION

In view of the foregoing amendment and remarks, it is respectfully submitted that pending claims 33 through 36 in the present application are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejection and a Notice of Allowance are respectfully requested.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/765,269 Confirmation No. : 7572
Applicants : Debra Ann MERRILL et al.
Filed : January 27,2004
Title : **Method for Producing a Gluten-Free Peptide Preparation and Preparation thus Obtained**
Group Art Unit : 1657
Examiner : Herbert J.LILLING
Customer No. : 28289

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Commissioner for Patents P.O.
Box 1450 Alexandria, VA
22313-1450

DECLARATION UNDER 37 C.F.R § 1.132

Sir:

1. I, Edward Allen Hunter, one of the inventors in the above-referenced patent application., submit this declaration in response to the Office Action dated March 1, 2007. As one of the inventors, I am fully familiar with the above-referenced application and all of the proceedings before the United States Patent and Trademark Office relating to the above-referenced application. Particularly, I have reviewed and considered the Office Action dated March 1,2007, the Auriol et al. (U.S. Patent No. 5,554,508) reference cited in the Office Action, and the above-reference application.

2. In the Office Action, the Examiner rejects claims 33-36 under 35 U.S.C. § 102(e) as anticipated by Auriol. However, Example 2 in Auriol would not produce a glutamine-rich gluten-free peptide preparation as claimed in the application for the reasons set forth below.

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3. The term "gluten-free" is defined in the specification as a "product when tested in an ELISA based on anti- Ω -gliadin antibodies yields a value of < 200 ppm" (Specification at page 2 lines 27-29). In contrast, Auriol Example 2 would produce a product with more than 300 gluten parts per million. This conclusion is supported by Experiment 5 in the Specification, which is an experiment that is similar to Auriol Example 2, as discussed in greater detail below.

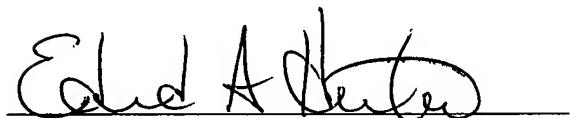
4. Auriol is directed to a process of making peptide esters by enzymatic alcoholysis (Column 1, lines 7-10). As indicated in Auriol, a protein substrate of plant origin is not necessarily pure (Column 3, lines 16-26). For example, wheat gluten contains approximately 45% gliadin (Column 3, lines 35-37). In teaching the method of forming peptide esters by enzymatic alcoholysis, Auriol discloses an example of an alcoholysis reaction of wheat gluten peptides (Example 2). The wheat gluten in Auriol Example 2 was first hydrolyzed with Alcase at pH of 8. The hydrolysate was then re-suspended in a 70% solution of n-propanol, more Alcase was added, and the pH was adjusted to 5.1. The mixture was incubated for 20 hours at 25°C. After the incubation was completed, the Alcase was denatured by adjusting the pH to 3.5 and heating the mixture to 50°C. The n-propanol was removed via evaporation, and the remaining aqueous suspension was adjusted to a pH of 6.0 then filtered.

5. In sum, Auriol Example 2 teaches enzymatic alcoholysis of wheat gluten at a pH of 8.0 and 5.1, and filtering the solution at a pH of 6.0. Similar to Auriol Example 2, Experiment 5 in the instant application adjusted the pH before filtration to 6.5 (Specification at page 6 lines 20-26). The resulting product from Experiment 5 had more than 300 gluten parts per million. A product with more than 300 gluten parts per million is not a gluten-free product as defined by the Specification. Since Experiment 5 in the instant application is similar to Auriol Example 2, Auriol Example 2 likewise would not produce, disclose, or suggest, a gluten-free peptide product as defined by the Specification, and therefore does not teach a gluten-free peptide preparation.

6. For these reasons, I respectfully submit that the invention as claimed in the instant application is novel over Auriol.

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7. I declare further that all statements made herein are true to my knowledge; and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Edward Allen Hunter

June 15 2007

Date